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MELLER, MICHAEL V	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/038,894
Filing Date: March 11, 1998
Appellant(s): STOUGHTON ET AL.

Stephanie Seidman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/5/2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: the 35 USC 103 rejection is dropped. The 35 USC 112, second paragraph rejections concerning "cell activation" and "if elevated" are dropped as well.

(7) Grouping of Claims

The rejection of claims 10-18, 32-36, 38, 41 and 42 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 32-36, 38, 41, 42 stand finally rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There is no support for the phrase, "thereby preventing a disease" in the specification. The specification does not give any evidence to support that the disease is prevented. No data or other evidence can be found that such diseases would be prevented in animal models or other models. Without such support, the claims are not enabled by the instant specification. To prevent a disease is to totally stop the disease from ever occurring. Appellant has not provided evidence that the disease is completely and utterly stopped and will never occur. In fact, there is no evidence on the record that such a method can even be practiced. There is no art on the record to state that such diseases/disorders can be prevented. How can one stop Alzheimer's from occurring ? If one knew how to prevent an incurable disease such as Alzheimer's then the literature would be replete with such information which it is not.

Claims 10-18, 32-36, 38, 41 and 42 stand finally rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are

elevated using futhan, does not reasonably provide enablement for any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are elevated, using futhan, but is not enabled for any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation .

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation to see if they could perform the claimed processes. With knowing only one activation lowering therapy, one condition to treat it with and only one type of assay in which to determine if it is necessary, one of ordinary skill in the art would not know what other conditions could be treated, what other therapies could be used or what other assays could be used to determine if such a method would work. Simply because such a method works with this combination does not mean that it will work for any and all combinations. The area of biotechnology is highly unpredictable since the human body in and of itself is very unpredictable.

Applicant has only shown treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are elevated, using futhan. With

only knowing this one combination of steps to yield the claimed method, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given this one combination.

The state of the art is that there is no art. There is no guidance on which assay would be useful for which disease/condition. To know which assay to use for whatever disease ranging from a bruise to Alzheimer's is not known in the art, and thus no guidance for one of ordinary skill in the art which assay if any, would be effective to carry out the claimed method.

Claims 10-18, 32-36, 38, 41, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is meant by "administering activation lowering therapy". Is this a method or a compound which is being administered ? Activation of what ? Applicant is still not clear what is being administered, a compound a method, what, What specifically is being administered to create such a desired effect.

It is also not clear what is meant by "preventing a disease or disorder" ? For the disease to be prevented the disease would have to be totally prevented, see above arguments. From reading the specification this is not what has happened. Thus, it is unclear how the claim is to be interpreted since prevention is not taught and one of

ordinary skill in the art would assume that the disease is totally absent when it is prevented.

(11) Response to Argument

Concerning the first 35 USC 112, first paragraph rejection, appellant first refers the examiner to page 32, lines 10-17; page 137, line 25 to page 138, line 2; and page 144, line 20 of the specification to allegedly provide support for the language "thereby preventing a disease or disorder" in claim 32.

It is first noted that this is the first time that appellant has shown this support in the specification.

While the support is noted, there is no evidence, i.e. data, that absolutely proves that any and all of the many different diseases or disorders under the sun can be prevented by using appellant's invention. Appellant points to a very specific example in the specification wherein rats were administered a pancreatic homogenate which supposedly puts the rats into shock. Appellant then claims that the rats died if they were not administered the Futhan (the protease inhibitor) with the pancreatic homogenate. Appellant states that the rats recovered after a brief bout of hypotension. These results do not prove much. In fact, the rats could have died from the bout of hypotension that the futhan and the pancreatic homogenate put the rat through. In other words, it is not

clear on the record that in every case a disease or disorder was prevented, in fact, in appellant's own specification appellant admits that this is not true since appellant states that the rat went through a bout of hypotension which is a disease or disorder which was not prevented. So, in fact, appellant has provided absolutely no conclusive evidence to support an extremely broad and unsupported claim set.

Concerning the second 35 USC 112, first paragraph rejection, appellant has argued that the examples in the specification allegedly provide one of ordinary skill in the art with enough information so that one of ordinary skill in the art can figure out how to make and use the other many possibilities of the invention.

While this is very interesting on its face, when one actually looks at the claims one can see that the claims encompass alterations in one's lifestyle to reducing stress as a means of "activation lowering therapy" which reads on taking a day off from work. This is a completely different type of "activation lowering therapy" to dialysis. Why would one of ordinary skill in the art think that if one can take a day off from work that that would also mean that that dialysis would also be effective in practicing this method.

Further, the invention is broadly claimed in its claiming of the "disease or condition". The disease or condition can range from trauma (which is vague and broad in and of itself) to stroke. Why would one of ordinary skill in the art think if the method can be used to treat trauma which encompasses a bruise to treating Alzheimer's ? There is simply no correlation between the allegedly "closely related" specieis that appellant is claiming.

Finally appellant is claiming a very broadly defined, "assessing treatment options for a disease or condition by measuring cell activation levels in a subject". This reads on just about anything as well. Even if one of ordinary skill in the art did envision one particular type of assay for assessing cell activation levels in a patient as argued by appellants on page 29 of the brief, one of ordinary skill in the art would not know which assay to use to measure such levels for a person who has a bruise versus someone who has Alzheimer's. The two conditions/diseases are completely unrelated and share no commonality in anyway. Thus, to come to some common assay or know which assays could be used for either is simply not known. If one knows that a particular assay is useful to detect low activation cell levels in a person who has Alzheimer's how can one of ordinary skill in the art know from that which assay might be of assistance to him in finding out which activation cells levels might be elevated in a person who has a bruise totally unrelated to Alzheimer's. They are completely different disease/disorders and such share no commonalities at all.

The state of the art is that there is no art. There is no guidance on which assay would be useful for which disease/condition. Appellant tries to offer the argument that one of ordinary skill in the art would really know which assay to use for whatever disease ranging from a bruise to Alzheimer's but the fact of the matter is that there is no art, and thus no guidance for one of ordinary skill in the art which assay if any, would be effective to carry out the claimed method.

Appellant argues that the 35 USC 112, second paragraph rejection is allegedly in error since appellant believes that one of ordinary skill in the art would know what "administering activation lowering therapy" means. Fact is, since the term has such a broad meaning as is evidenced by the appellants themselves in their broad definition of the term on page 19 of the specification, how can one of ordinary skill in the art know what it really encompasses since it reads on everything from taking a day off from work to taking futhan. A lifestyle change could also read on moving to Hawaii or becoming a monk. Is that really what the invention is ? This term is confusing and appellant has not amended it to make the true meaning of the term clear.

It is still not clear what "preventing a disease or disorder" means. Appellant refers the examiner to the argument above with regard to preventing and the above 35 USC 112, first paragraph rejection, but as pointed out by the examiner above, the specification does not even provide the support that appellant needs to show that they are enabled for preventing. As shown by appellants' comments, they themselves are confused as to what prevention means. Prevention means to completely stop something from happening otherwise it occurs and was not prevented.

Thus, it is unclear how the claim is to be interpreted since prevention is not taught by the specification and one of ordinary skill in the art would assume that the disease is totally absent when it is prevented.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Art Unit 1654

MVM

January 14, 2005

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